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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/432,503	11/02/1999	THOMAS R. CECH	15389-002611	1130

7590

08/26/2002

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EXAMINER

RAMIREZ, DELIA M

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 08/26/2002

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/432,503

Applicant(s)

CECH ET AL.

Examiner

Delia M. Ramirez

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 6/10/2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 41-57 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 41-57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11/2/1999 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 14, 16.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Status of the Application

Claims 41-57 are pending.

Applicant's amendment of claims 41, 43, 47, 50, 56 in Paper No. 15, filed on 6/10/2002 is acknowledged.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Priority

1. Acknowledgment is made of a claim for foreign priority under 35 U.S.C. 119(a)-(d) to PCT/US97/17885 and PCT/US97/17618 filed on 10/01/1997
2. Acknowledgment is made of a claim for domestic priority under 35 U.S.C. 120 or 121 to US application No. 08/915503, 08/912951, 08/911312, filed on 8/14/1997, 08/854050 filed on 5/9/1997, 08/851843 filed on 5/6/1997, 08/846017 filed on 4/25/1997, 08/844419 filed on 4/18/1997, and 08/724643 filed on 10/1/1996.

Information Disclosure Statement

3. The information disclosure statement (IDS) submitted on 6/10/2002 was filed after the mailing date of the first Office Action on the merits Paper No. 11 on 1/15/2002. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

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4. The information disclosure statement (IDS) submitted on 8/7/2002 was filed after the mailing date of the first Office Action on the merits Paper No. 11 on 1/15/2002. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Drawings

5. The drawings have been reviewed and were objected under 37 CFR 1.84 or 1.152. According to PTO records, a Notice of Draftsperson's Patent Drawing Review was sent to Applicants with Paper No. 11, mailed on 1/15/2002. In the event that Applicant did not receive this notice, another Notice of Draftsperson's Patent Drawing Review is being sent with this Office Action. Applicant is required to submit the drawing corrections within the time period set in the attached Office communication. See 37 CFR 1.85(a). Failure to take corrective action within the set period will result in ABANDONMENT of the application. In addition, if amendments to the specification are needed due to drawing corrections, Applicant is requested to submit such amendments while the case is being prosecuted to expedite the processing of the application.

Claim Objections

6. Claims 44, 51 and 57 are objected to because of the following informalities: the word "of" should be inserted between the words "method" and "claim". Appropriate correction is required.

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7. Claim 47 is objected to because it is a duplicate of claim 43. For examination purposes, it will be assumed that claim 47 refers to claim 45 instead of claim 41. Appropriate correction is required.

Claim Rejections - 35 USC § 112, Second Paragraph

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claim 41, 43, 47, 50 and 56 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. Claim 41 is indefinite in the recitation of “wherein DNA having the sequence of the polynucleotide hybridizes to DNA having the sequence of SEQ ID NO: 1” as it is confusing. The claim first recites “a recombinant polynucleotide encoding a telomerase reverse transcriptase” therefore, it is understood that it is this polynucleotide (encodes the protein) which hybridizes to DNA having the sequence of SEQ ID NO: 1. It is suggested that the term be replaced with “wherein the polynucleotide hybridizes to DNA having the sequence of SEQ ID NO: 1” or similar. Appropriate correction is required.

11. Claims 43, 47, 50, and 56 are indefinite in the recitation of “further comprising selecting the cell because it expresses increased telomerase activity as a result of introducing the polynucleotide” as it is confusing. It is suggested that the claim be amended with more clear language such as “further comprising selecting cells which express an increased level of

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telomerase activity as a result of introducing the polynucleotide” or similar. Correction is required.

Claim Rejections - 35 USC § 112, First Paragraph

12. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. Claims 41-57 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

14. This rejection was explained in previous Office Action Paper No. 11, mailed on 1/15/2002.

15. Applicants argue that the instant claims are directed to a method for increasing the proliferative capacity of the cell and not to a method for immortalizing cells. As such, Applicants assert that the state of the art shows examples of increased proliferation in cells transformed with a polynucleotide encoding hTERT (human telomerase reverse transcriptase) including references presented by the Examiner in previous Office Action Paper No. 11.

Furthermore, Applicants provided references published after the filing date of the application, which in their opinion, support the argument that any mammalian cell can at least increase their ability to proliferate if transformed with DNA encoding hTERT. Also, Applicants have

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submitted reference BI in IDS Paper No. 16, filed on 8/7/2002 as evidence to support enablement of the claimed method *in vivo*.

16. Applicant's arguments have been fully considered but are not deemed persuasive to overcome the rejection. While it is agreed that the claims are directed to a method for increasing proliferation and not a method for immortalizing cells, neither the references presented nor the art cited previously teach or suggest practicing this method *in vivo* as encompassed by the claims. At best, the references provided by Applicants only support the argument that transformation of a mammalian cell with DNA encoding hTERT may lead to increased proliferation *in vitro*. Neither the state of the art at the time the invention was made nor the specification teach or suggest how to practice the claimed invention *in vivo*. In regard to reference BI (US application No. 10/143536), the Examiner has considered the reference, however, it is not deemed sufficient to overcome the enablement rejection as it relates to the claimed method *in vivo* as this application fails to establish enablement of the current claims at the time of filing of the instant application. As indicated previously, neither the specification of the instant application nor the specification of applications to which the current application claims priority to, disclose and/or enable one of skill in the art to practice the claimed method *in vivo*.

Double Patenting

17. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686

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F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

18. Claims 41-47 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 7-8 of U.S. Patent No. 6,337,200. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 41-47 of the instant application are generic to all that is recited in claims 7 and 8 of U.S. Patent No. 6,337,200. Claims 41-47 of the instant application are drawn to a method for increasing the proliferative capacity of a mammalian cell by introducing a DNA encoding a telomerase reverse transcriptase protein, a variant or a fragment having telomerase catalytic activity, wherein the DNA encoding the protein, variant or fragment hybridizes to the DNA of SEQ ID NO: 1 under specific stringent conditions. Claims 7 and 8 of U.S. Patent No. 6,337,200 are drawn to a method for increasing the proliferative capacity of a human cell in vitro which comprises expressing a polynucleotide encoding a variant of the polypeptide of SEQ ID NO: 2 wherein the variant has processive catalytic activity and

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wherein the variant comprises a deletion of at least 10 amino acids of specific regions of SEQ ID NO: 2. The polynucleotide of SEQ ID NO: 1 encodes the polypeptide of SEQ ID NO: 2 in both, the instant application and the US patent. Therefore, the polynucleotide encoding the variant of SEQ ID NO: 2 in claims 7 and 8 of US Patent No. 6,337,200 will hybridize to the polynucleotide of SEQ ID NO: 1 under the conditions recited in the claims of the instant application. In addition, since the variant polypeptide of US Patent No. 6,337,200 is the polypeptide of SEQ ID NO: 2 which has been modified with deletions in specific regions, such polypeptide variant can be a naturally occurring reverse transcriptase as long as the activity is maintained. Consequently, claims 7 and 8 of US Patent No. 6,337,200 fall within the scope of claims 41-47 of the instant application as written.

19. Applicant is advised that should claim 43 be found allowable, claim 47 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Conclusion

20. No claim is in condition for allowance.

21. Applicants are requested to submit a clean copy of the pending claims (including amendments, if any) in future written communications to aid in the examination of this application.

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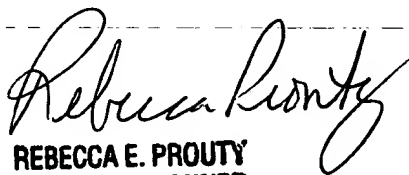
22. Certain papers related to this application may be submitted to Art Unit 1652 by facsimile transmission. The FAX number is (703) 308-4556. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If Applicant submits a paper by FAX, the original copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez whose telephone number is (703) 306-0288. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy can be reached on (703) 308-3804. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Delia M. Ramirez, Ph.D.
Patent Examiner
Art Unit 1652

DR
August 22, 2002


REBECCA E. PROUTY
PRIMARY EXAMINER
GROUP 1800
1600